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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,327	05/09/2001	Robert J. Levy	047172-0170	2799

7590

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/851,327	LEVY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Scott Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The claims embrace two distinct sets of invention, the first set of inventions (Set A) is directed to delivery of a nucleic acid which encodes a product, classified in class 435, subclass 455; and the second set (Set B) is directed to delivery of antisense or ribozyme nucleic acid, classified in class 435, subclass 375. Within each set of inventions, each invention is directed to the use of a particular "agent". The groups are as set forth below listing the claims pertaining to each group as well as the particular "agent" which distinguishes each invention from the others.

Set A - wherein the nucleic acid delivery system comprises a nucleic acid which encodes a product.

- A1. Claims 1-5, 10-12, 14, 15, 21, 27-33, wherein the agent is a second nucleic acid encoding TB4 or tenascin C.
- A2. Claims 1, 3-6, 12, 14, 15, 21-23, 26, 27, 28, 32, 33, wherein the agent is denatured collagen.
- A3. Claims 1, 3-5, 7-9, 12, 14-16, 18, 21, 26-28, 32, 33, wherein the agent is TB4 or tenascin C.
- A4. Claims 1, 3-5, 12, 13, 27, 28, 32, 33, wherein the agent is a DNAase I inhibitor.

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- A5. Claims 1, 3-5, 12, 14-17, 27, 28, 32, 33, wherein the agent is an ion channel blocker.
- A6. Claims 1, 3-5, 12, 14, 19, 20, 27, 28, 33, wherein the agent is beryllium fluoride or a cadmium salt.
- A7-A23. Claims 1, 3-5, 12, 14, 21, 24, 27, 28, 32, 33, wherein the agent is a modulator of an integrin, FAK, Src, Grb2, Ras, Sos, Raf, Cav, Shc, Cdc42, Rac, RhoA, MEK, MAPK, MRK 1/2, Erk1/Srf complex, JNK activated AP-1 complex, respectively (i.e. integrin - group A7, FAK - group A8, and so on).
- A24. Claims 1, 3-5, 12, 14, 25, 27, 28, 32, 33 wherein the agent is a cytochalasin.
- A25. Claims 1, 3-5, 12, 26-28, 33, wherein the agent is a TB4 gene promoter.
- Set B - wherein the nucleic acid delivery system comprises an antisense or ribozyme nucleic acid
- B1. Claims 1-5, 10-12, 14, 15, 21, 27-33, wherein the agent is a second nucleic acid encoding TB4 or tenascin C.
- B2. Claims 1, 3-6, 12, 14, 15, 21-23, 27, 28, 32, 33, wherein the agent is denatured collagen.
- B3. Claims 1, 3-5, 7-9, 12, 14-16, 18, 21, 26-28, 32, 33, wherein the agent is TB4 or tenascin C.
- B4. Claims 1, 3-5, 12, 13, 27, 28, 32, 33, wherein the agent is a DNAase I inhibitor.

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- B5. Claims 1, 3-5, 12, 14-17, 27, 28, 32, 33, wherein the agent is an ion channel blocker.
- B6. Claims 1, 3-5, 12, 19, 20, 27, 28, 33, wherein the agent is beryllium fluoride or a cadmium salt.
- B7-B23. Claims 1, 3-5, 12, 21, 24, 27, 28, 32, 33, wherein the agent is a modulator of an integrin, FAK, Src, Grb2, Ras, Sos, Raf, Cav, Shc, Cdc42, Rac, RhoA, MEK, MAPK, MRK 1/2, Erk1/Srf complex, JNK activated AP-1 complex, respectively (i.e. integrin - group B7, FAK - group B8, and so on).
- B24. Claims 1, 3-5, 12, 25, 27, 28, 32, 33 wherein the agent is a cytochalasin.
- B25. Claims 1, 3-5, 12, 26-28, 33, wherein the agent is a TB4 gene promoter.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 86.05 for inventive groups that are directed to different methods or products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

The inventions of Set A are directed to delivery of nucleic acids which encode an active product, whereas the inventions of Set B are directed to delivery of nucleic acids which inhibit

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expression of an endogenous product. These two classes of nucleic acids are structurally and functionally different, and the goals of the two sets of invention are different.

Each of the inventions of A1-A25 or B1-B25 are directed different agents which lead to a common effect - enhancing cytoskeletal permissiveness for transfection. Each agent differs structurally and functionally from every other method and achieves the common effect by a different mechanism.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper between the inventions of Set A and Set B.

Because these inventions are distinct for the reasons given above and the search required for agent is not required for the other agents, restriction for examination purposes as indicated is proper between each of the inventions of Set A or each of the inventions of Set B.

Claims 1, 3-5, 12, 27, 28, and 33 link(s) inventions A1-A25 and B1-B25. Claim 14 links inventions A1-A3, A5-A24, B1-B3, and B5-B24. Claim 21 links inventions A1-A3, A7-A23, B1-B3, and B7-B23. Claim 24 links inventions A7-A23 and B7-B23. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations

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of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

*In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

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Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Scott D. Priebe*

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Art Unit 1632